IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Cardizem CD

STATE OF NEW YORK, *ex rel.*
Attorney General ELIOT SPITZER,

STATE OF MICHIGAN, *ex rel.*
Attorney General JENNIFER GRANHOLM,

STATE OF ARIZONA, *ex rel.*
Attorney General JANET NAPOLITANO,

STATE OF CALIFORNIA, *ex rel.*
Attorney General BILL LOCKYER,

DISTRICT OF COLUMBIA, *ex rel.*
Corporation Counsel ROBERT R. RIGSBY,

STATE OF IDAHO, *ex rel.*
Attorney General ALAN G. LANGE,

STATE OF INDIANA, *ex rel.*
Attorney General STEVE CARTER,

STATE OF MAINE, *ex rel.*
Attorney General G. STEVEN ROWE,

STATE OF MINNESOTA, *ex rel.*
Attorney General MIKE HATCH,

STATE OF NEW MEXICO, *ex rel.*
Attorney General PATRICIA A. MADRID,

STATE OF NORTH CAROLINA, *ex rel.*
Attorney General ROY COOPER,

STATE OF OKLAHOMA, *ex rel.*
Attorney General W.A. DREW EDMONDSON,

STATE OF UTAH, *ex rel.*
Attorney General MARK L. SHURTLEFF,

01-71835

COMPLAINT

CIVIL ACTION NO. _____

JULIAN ABELE COOK, JR.

MAGISTRATE JUDGE SCHEER

STATE OF VERMONT, *ex rel.*
Attorney General WILLIAM H. SORRELL,

STATE OF WASHINGTON, *ex rel.*
Attorney General CHRISTINE O. GREGOIRE,

STATE OF WEST VIRGINIA, *ex rel.*
Attorney General DARRELL VIVIAN McGRAW, JR.,

Plaintiffs,

v.

AVENTIS S.A.,
successor in interest to Hoechst Aktiengesellschaft

AVENTIS PHARMACEUTICALS INC.,
successor in interest to Hoechst Marion Roussel, Inc.

CARDERM CAPITAL L.P.,

ANDRX CORPORATION,

Defendants.

I.
SUMMARY

1. The States of New York, Michigan, Arizona, California, Idaho, Indiana, Maine, Minnesota, New Mexico, North Carolina, Oklahoma, Utah, Vermont, Washington and West Virginia, by and through their Attorneys General, and the District of Columbia, by and through its Corporation Counsel, (collectively "Plaintiff States" or "States") bring this action in their proprietary capacities on behalf of departments, bureaus, and agencies of state government as injured purchasers or reimbursers; and as *parens patriae* on behalf of natural persons in their collective States, and their

respective States' quasi-sovereign interests in fair competition and the health of their citizenry, and/or in their sovereign capacities; against defendants Aventis S.A., successor in interest to Hoechst Aktiengesellschaft ("Hoechst AG"), Aventis Pharmaceuticals Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc. ("HMRI"); its subsidiary Carderm Capital, L.P. ("Carderm"); and Andrx Corporation. ("Andrx") (collectively "Defendants").

2. This action seeks relief for a series of anti-competitive and illegal acts, by which Defendants sought to delay or prevent the marketing of less expensive, generic alternatives to Cardizem CD, a highly profitable, brand-name drug for treatment of chronic chest pains and high blood pressure, and prevention of heart attacks.

3. On September 15, 1997, Defendant Andrx gained preliminary Food and Drug Administration ("FDA") approval for a generic version of Cardizem CD. Such preliminary approval would have enabled Andrx to enter the market with Cartia XT, its generic version of Cardizem CD, as of July 9, 1998. Instead, on September 24, 1997, Andrx entered into a Stipulation and Agreement with HMRI (the "Agreement"), under which HMRI agreed to make quarterly payments of millions of dollars in return for Andrx's agreement to keep its generic version of Cardizem CD off the market, and to refrain from selling any other drug that was the bioequivalent of Cardizem CD. Further, the Agreement required Andrx to maintain the application it had pending before the FDA at the same time it withheld its product, the effect of which was to keep other potential generic competitors from the market. As a result of this Agreement, HMRI paid Andrx nearly $90 million and in exchange, Andrx delayed the marketing of Cartia XT for nearly a year. The market entry of other generic drugs was also obstructed and consumers were deprived of lower-priced alternatives to Cardizem CD.

4. The Agreement between HMRI and Andrx was only one manifestation of a

systematic effort by HMRI to obstruct the market entry of competitors to Cardizem CD. HMRI also sought to prevent another drug manufacturer, Biovail Corporation ("Biovail"), from selling its own generic alternative to Cardizem CD. HMRI did so by reneging on a commitment to provide Biovail with the right to use data crucial to securing speedy FDA approval of its drug. On or about July 7, 1997, shortly before it concluded its agreement with Andrx, HMRI offered to pay Biovail to delay its sale of a generic version of Cardizem CD. This offer to Biovail was strikingly similar to the agreement that Hoechst and Andrx entered to delay generic competition.

5. The Defendants' allocation of the market for Cardizem CD and its bioequivalents constituted an unreasonable restraint of trade and a violation of the Sherman Act. Moreover, by means of the Agreement and other anti-competitive acts, HMRI engaged in a conspiracy to extend its statutorily granted monopoly on Cardizem CD beyond its proper expiration, and did in fact illegally maintain its monopoly on the market for Cardizem CD and its bioequivalents. Alternatively, by means of the Agreement and other anti-competitive acts, HMRI engaged in a conspiracy to extend its monopoly on once-a-day extended release diltiazem prescription drugs, and did in fact illegally maintain its monopoly on the market for once-a-day extended release diltiazem prescription drugs.

6. As a result of this illegal conduct, Plaintiff States, and natural persons residing therein, were deprived of equally effective, cheaper generic alternatives to Cardizem CD, and instead were forced to pay the monopoly price charged by HMRI for its brand-name drug. These actions deprived Plaintiff States and their consumers of a free and fair market for pharmaceutical products, were detrimental to the health of those citizens who could not afford to pay the higher prices charged by HMRI, and resulted in higher costs to government and other payers of healthcare expenses.

7. By this action, the States seek: 1) monetary relief to remedy and compensate them, and consumers residing therein, for the injuries they sustained as a result of Defendants' anti-competitive acts; and 2) equitable relief and civil penalties, including disgorgement of profits, to prevent Defendants from engaging in similar improper conduct in the future, and to restore the integrity of the marketplace.

II.
JURISDICTION AND VENUE

8. This Complaint, which alleges violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, is filed under, and jurisdiction is conferred upon this Court by, Section 4 of the Clayton Act, 15 U.S.C. § 15, and Section 16 of the Clayton Act, 15 U.S.C. § 26.

9. The Complaint also alleges violations of state antitrust, unfair competition and/or consumer protection statutes and related state laws. This Court has jurisdiction over those claims under 28 U.S.C. § 1367, and under the principles of supplemental jurisdiction. The federal and state law claims arise from a common nucleus of operative facts, and the entire suit commenced by this Complaint constitutes a single action which would ordinarily be tried in one judicial proceeding. The exercise of supplemental jurisdiction would avoid duplication and a multiplicity of actions, and should be exercised in the interests of judicial economy, convenience and fairness.

10. Venue in this district is proper under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). At all times relevant to this action, Defendants transacted business, did business, or were found in the Eastern District of Michigan. The claims alleged also arose, in part, in this judicial district.

III.
THE PARTIES

11. The States, by and through their Attorneys General, bring this action in their proprietary capacities on behalf of departments, bureaus, and agencies of state government as injured purchasers or reimbursers under Medicaid and other programs; as *parens patriae* on behalf of natural persons in their collective States; and on behalf of their respective States' quasi-sovereign interests in fair competition and the health of their citizenry.

12. Defendant Aventis S.A. is a French corporation with its office and principal place of business in Strasbourg, France. Aventis S.A. was formed in December 1999, following the merger of Hoechst AG, a German corporation, and Rhone-Poulenc, S.A, a French corporation. Aventis S.A. owns approximately 97 percent of the outstanding shares of Hoechst A.G.

13. Defendant Aventis Pharmaceuticals Inc. is a Delaware corporation with its office and principal place of business in Parsippany, New Jersey ("Aventis"). Aventis is an indirect, wholly owned subsidiary of Aventis S.A. Until the merger of Hoechst A.G. and Rhone-Poulenc, S.A, Aventis was known as HMRI, which was an indirect, wholly owned subsidiary of Hoechst A.G. Aventis is, and HMRI was, responsible for, among other things, developing, distributing, advertising and selling Cardizem CD throughout the United States. On information and belief, Aventis does business throughout the United States, and is the successor in interest to HMRI in all respects.

14. Defendant Carderm Capital L.P. ("Carderm") is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm was directly or indirectly owned or controlled by HMRI. On information and belief, Carderm is now directly or indirectly owned or controlled by Aventis. Carderm holds the patents covering Cardizem CD and licensed them to HMRI. On information and belief, the patents on

Cardizem CD held by Carderm are now licensed to Aventis.

15. Defendant Andrx Corporation is a Delaware corporation with its office and principal place of business at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida 33314. Andrx develops, manufactures and markets controlled-release drugs. Andrx does business throughout the United States through its distribution subsidiary, Anda Generics, which sells generic drugs to independent pharmacies and regional drug chains. Andrx developed a generic bioequivalent of Cardizem CD, called Cartia XT, which was fully approved by the FDA for sale in the United States in June 1999.

IV.
ANTICOMPETITIVE CONDUCT

A. The Statutory Regime for Entry of Generic Drugs

16. A generic drug is a pharmaceutical product comparable to a brand-name drug in dosage, form, strength, route of administration, quality, performance characteristics and intended use. It is typically sold, however, at a substantial discount from the brand-name drug's price. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an AB rating.

17. Cardizem CD is available in the United States only by prescription written by a physician. When a prescription is written for a brand-name drug such as Cardizem, a pharmacist can fill the prescription only by dispensing either the brand-name drug or its AB rated generic.

18. Under most insurance plans, a pharmacist will substitute an AB rated generic version of a prescribed brand-name drug, when available, unless the physician has indicated "DAW" or "dispense as written" on the prescription. Similarly, many State agencies for which Plaintiffs seek to recover damages and other monetary relief have policies or practices which allow, or require, that

they purchase cheaper, bioequivalent, generic alternatives to brand-name drugs when they are available, or set a maximum allowable cost ("MAC") price which reflects the less expensive generic product prices.

19. In order for Cardizem CD or its generic equivalent products to be eligible for utilization under state Medicaid programs, the manufacturer must enter a rebate agreement either directly with the State or with the United States Secretary of Health and Human Services, acting on behalf of the State. HMRI has entered such a contract which, upon information and belief, is substantially similar in form to the contract attached as Appendix A.

20. Upon information and belief, HMRI has agreed under the contract, "to calculate and make a Rebate Payment to each State Medicaid Agency for [HMRI's] Covered Outpatient Drugs [including Cardizem CD] paid for by the State Medicaid Agency during a quarter." Appendix A, paragraph II(a). Andrx and other manufacturers of generic versions of Cardizem CD have entered similar contracts. Under these contracts, each state directly invoices the manufacturer based upon the number of units paid for by the state in each calendar quarter.

21. The total cost to a State Medicaid agency for the utilization of Cardizem CD or its generic equivalents is a function of a reimbursement amount paid by the State to pharmacies where the drug was dispensed minus the contractually agreed rebate payment, which is invoiced by the State Medicaid Agency directly to the manufacturer. To the extent that Defendants' illegal activities have increased this total cost, State Medicaid agencies are injured in their business or property as set forth in 15 U.S.C. § 15.

22. The entry of a generic drug into the market can significantly lower the costs incurred

by consumers of the brand-name drug. The first generic competitor usually prices its product approximately 20% lower than the equivalent brand-name drug, while subsequent generic entrants can cause the price of the initial generic offering to fall as much as 80%. The manufacturer of the brand-name drug will typically suffer a substantial decline in its market share immediately after generic alternatives are made available to purchasers. Third party payers, such as government prescription drug assistance programs, also often charge a lower consumer co-payment on purchases of generic drugs than they do for the drugs' brand-name equivalents.

23. Before a drug may be marketed in the United States, the manufacturer must obtain FDA approval. To streamline the approval process, and thereby encourage the development of cheaper, generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, a prospective generic entrant may gain FDA approval by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA filer must certify that, as of market entry, the generic drug will not infringe any patent for an existing drug listed in *Approved Drugs with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," a compendium of such patents maintained by the FDA. 21 U.S.C. §355(j)(2)(A)(vii). The ANDA filer may certify that patent information on the brand-name drug has not been filed, or that such patent has expired, or that the generic will not be marketed until the date on which such patent will expire. Alternatively, the ANDA filer may make a "Paragraph IV Certification," by which the applicant asserts that the brand-name patent is invalid, or not infringed. 21 U.S.C. §355(j)(2)(A)(vii)(IV). The applicant must provide notice of its Paragraph IV Certification to the maker of the brand-name drug.

24. To provide an impetus to challenge patents and/or design around them, the Act entitles the first Paragraph IV certified ANDA filer to a 180-day period of marketing exclusivity (the "Exclusivity Period"), during which the FDA may not grant final approval to any other generic manufacturer's ANDA regarding the same brand-name drug. The Exclusivity Period does not begin to run until either the first applicant enters the market with its product, or a court enters a final judgment that the patent(s) subject to the Paragraph IV Certification are invalid or not infringed.

25. The Act also makes the filing of a Paragraph IV Certification an "artificial act of infringement" for purposes of patent law. 34 U.S.C. § 271(e)(2). If the patent holder commences an infringement action within 45 days of receiving the Paragraph IV Certification, FDA approval is automatically stayed until the earlier of (i) the expiration of the relevant patent, (ii) 30 months from the date of receipt of the Paragraph IV certification, or (iii) a final judicial determination of non-infringement or invalidity of the patent. If the 45-day period elapses without an infringement action, final FDA approval is not contingent on, and will not be delayed by, any subsequently filed patent infringement action.

B. HMRI's Acquisition and Maintenance of its Exclusive Hold on Cardizem CD.

26. Cardizem CD is prescribed for the treatment of chronic chest pains and high blood pressure, and for the prevention of heart attacks. Once prescribed, Cardizem CD is generally taken by a patient for years.

27. The active ingredient in Cardizem CD is diltiazem hydrochloride ("diltiazem"). The United States patent on diltiazem expired in November 1992. However, prior to the expiration of the patent on diltiazem, Carderm made a patent application claiming the Cardizem CD dissolution profile, which is the amount of diltiazem released into the blood over a specific period of time. The

application claimed that 0-45% of the total diltiazem in Cardizem CD was released within 18 hours of ingestion, and not less than 45% was released over a 24 hour period, as measured in a hydrochloric acid test (the "dissolution profile"). On November 28, 1995 the U.S. Patent and Trademark Office issued United States Patent No. 5,470,584 ("the 584 patent") to Carderm, which licensed it to HMRI. However, the 584 patent did not in any way extend the patent on the active ingredient, diltiazem, which came "off patent" in 1992 and is in the public domain. Accordingly, since the patent expired diltiazem has been in the public domain.

28. Diltiazem-based drugs have been available for treatment of hypertension as early as 1982, but the immediate release formulations of the first diltiazem drugs required that patients take three or four doses per day. As a result, the incidence of non-compliance was high, and users often suffered from side effects caused by undesirable fluctuations of diltiazem in the blood. Cardizem CD, however, uses a delay-release formulation, and therefore need be taken only once per day.

29. Cardizem CD's single administration of diltiazem over the course of a day is based on a sustained release delivery and absorption method claimed in United States patent no. 5,002,776 (the "776 patent") and United States patent no. 4,894,240 (the "240 patent") (collectively termed the "controlled absorption formulation patents"). Marion Merrell Dow Corporation ("MMD") and Carderm were the licensees of the controlled absorption formulation patents.

30. When it was introduced in 1992, Cardizem CD immediately captured a substantial share of the market. Through 1999, Cardizem CD dominated the once-a-day diltiazem prescription market, with sales in the United States of over $700 million in each of 1996 and 1997, and a market share of almost 80%. During this period, Cardizem CD was the largest revenue producer for HMRI.

As a result, there was intense pressure on HMRI's management to delay market entry by generic competitors of Cardizem CD until HMRI produced another drug which generated comparable profits.

31. Cardizem CD was first developed and manufactured by Marion Merrell Dow Corporation ("MMD")MMD. HMRI initially obtained the rights to another once-daily diltiazem-based drug known as Tiazac, via a Rights and Supply Agreement with Biovail.

32. MMD brought an action against HMRI and Biovail, alleging that Tiazac infringed its patent for Cardizem CD. At first, HMRI contested the suit. But in June 1995, HMRI purchased MMD from its parent, Dow Chemical Corporation, thereby acquiring the right to market Cardizem CD. It then terminated the joint venture with Biovail.

33. Biovail responded by suing HMRI and Carderm for breach of contract and antitrust violations. The parties eventually settled the suit and, as part of the settlement, HMRI entered into a broad covenant not to sue Biovail for actions related to diltiazem-based drugs.

34. The FTC launched an investigation into HMRI's purchase of MMD, which was ultimately settled by consent order. To rectify the anticompetitive effects of the merger, the order specifically directed HMRI to provide Biovail with a right of reference for the toxicology data that MMD had submitted to the FDA in support of its initial New Drug Application ("NDA") for Cardizem. Toxicology data demonstrates a drug's safety and efficacy, and is normally quite time consuming and expensive to generate. By compelling HMRI to authorize use of its toxicology data as support for any NDA filed by Biovail for a diltiazem-based product, the FTC effectively allowed Biovail to market a generic version of Cardizem CD by filing an NDA, rather than an ANDA. Normally, FDA approval of an ANDA is much faster than of an NDA, but with the right of reference, Biovail's NDA could have been approved as quickly as an ANDA. Further, use of an NDA would

mean that Biovail's generic drug application would not be subject to the Hatch-Waxman ANDA regulations, including the "artificial act of infringement" claim based on notice of Paragraph IV certification, the statutory 30 month stay or the Exclusivity Period rules.

35. In accordance with the consent order, HMRI sent a letter to the FDA on December 18, 1995, advising the agency that Biovail was entitled to reference toxicology data from its Cardizem NDA, and any supplemental NDAs "related to that product." The FDA subsequently confirmed to Biovail that the right of reference granted by HMRI was broad enough to cover "all future NDA submissions involving diltiazem-based drug products that Biovail might file."

36. HMRI did not, however, abide by its promise to the FTC, or the representations set forth in its letter to the FDA. Instead, on July 11, 1996, HMRI informed the FDA by letter that the right of reference granted to Biovail by HMRI extended only to Tiazac, and that Biovail could not use the right of reference for other diltiazem-based products, including Cardizem CD. Neither Biovail nor the FTC were informed by HMRI that it had chosen to reinterpret its obligations under the consent order and retreat from its earlier position.

37. Biovail did not learn of HMRI's revised stance until informed of it by the FDA by letter dated November 8, 1996. At the time, Biovail had been planning to file both an ANDA and an NDA for its version of Cardizem CD. Once HMRI reneged on the commitment it had given the FTC, Biovail could not seek approval via an NDA without compiling its own toxicology data, which would have required the expenditure of substantial funds and entailed significant delay.

38. In June 1997, Biovail filed an ANDA for a generic version of Cardizem CD. (The first filer, Andrx, had filed its ANDA for a generic equivalent of Cardizem CD on September 22, 1995, over one and one half years earlier.) On August 1, 1997, just prior to the end of the forty-five

day period during which HMRI could delay the generic product's entry by filing suit, HMRI contacted Biovail and initiated a series of meetings in which HMRI sought to forestall Biovail's sale of a generic competitor to Cardizem CD.

39. During these meetings, HMRI offered to pay Biovail a substantial sum of money in exchange for Biovail's agreement to delay the marketing of its generic competitor to Cardizem CD. In addition, HMRI promised that it would provide Biovail with a lucrative license to "develop" and sell one of its other drugs, Probucol. On information and belief, it was intended that this "license" agreement to develop Probucol would contain no development milestones or targets and would have been a non-refundable payment by HMRI to Biovail, even if Biovail did nothing to develop Probucol. HMRI also insisted, as part of their agreement, that Biovail not contact Andrx, the first filer and holder of the rights to the Exclusivity Period for a generic Cardizem CD. HMRI refused, however, to grant Biovail the right of reference which would have allowed the FDA to grant final approval of Biovail's generic alternative to Cardizem CD by means of an NDA, and the parties failed to reach agreement.

40. Because HMRI had previously entered into a covenant not to sue Biovail, it did not bring an infringement action against Biovail. Nonetheless, because Biovail's ANDA was subordinate to Andrx's rights as the first filer of an ANDA, the entry of Biovail's generic alternative to Cardizem CD was delayed by the terms of the market division agreement entered into by HMRI and Andrx, the details of which are set forth below.

C. The Competitive Threat by Andrx

41. In August 1995, prior to filing its ANDA and Paragraph IV Certification for a generic version of Cardizem CD, Andrx gave samples of its product to HMRI so that HMRI could test

Andrx's version and confirm that it did not infringe the patents claiming Cardizem CD. Andrx shared its samples with HMRI with the hope of avoiding infringement litigation. In addition, Andrx filed a patent application with the United States Patent & Trademark Office (the "US PTO") on March 24,1995 claiming its diltiazem controlled release formulation. On October 22, 1996, the US PTO issued United States Patent No. 5,567,441 to Andrx.

42. On September 22, 1995, Andrx became the first manufacturer to file a Paragraph IV Certified ANDA for a generic alternative to Cardizem CD with the FDA.

43. After filing its ANDA with the FDA, Andrx notified HMRI of its Paragraph IV Certification, which stated that the Andrx product did not infringe any unexpired patents listed in the Orange Book concerning Cardizem CD.

44. Two months after Andrx filed its ANDA, on November 28, 1995 the US PTO issued United States Patent No. 5,470,584 (the "584 patent") to HMRI's subsidiary, Carderm was granted the 584 patent on the 0-45% over 18 hours dissolution profile for Cardizem CD. The 584 patent claimed a dissolution rate from 0-45% of total diltiazem released after 18 hours and not less than 45% of total diltiazem released after 24 hours. The 584 patent was immediately listed by HMRI in the Orange Book as covering Cardizem CD.

45. On information and belief, the 584 patent was prosecuted and listed solely to give HMRI a basis for initiating sham litigation to delay and exclude Andrx and other generic manufacturers from competing with Cardizem CD. On information and belief, the Andrx product did not infringe on the 584 patent.

46. On January 31, 1996, HMRI and Carderm filed a patent infringement suit against

Andrx in the United States District Court for the Southern District of Florida, claiming that Andrx's generic product would infringe the 584 patent. The filing of the suit triggered the 30-month Hatch-Waxman Act waiting period, during which the FDA could not finally approve Andrx's product for marketing, unless the patent suit was fully resolved.

47. On April 4, 1996, Andrx amended its ANDA to increase the dissolution rate of its generic product to 55% over 18 hours ("Andrx's Amended ANDA"), thereby making its product even more distinct from Cardizem CD. The increased dissolution rate specified by Andrx was within the dissolution range that Carderm had specifically canceled from its application for the '584 patent. Andrx gave notice of this change to HMRI, which nonetheless persisted with its infringement litigation.

48. On information and belief, the change in the dissolution profile precluded HMRI from having a realistic expectation of success in the infringement suit. On information and belief, HMRI maintained its infringement action against Andrx with the intent of delaying the market entry of a generic competitor.

49. During the pendency of Andrx's Amended ANDA, a third generic manufacturer, Purepac, filed its ANDA in January 1997. HMRI responded by commencing a patent infringement action against Purepac, which stayed FDA approval of Purepac's product until July 1999.

50. During the first half of 1997, Andrx readied Cartia XT for sale. Andrx ordered machines, produced initial batches of product, prepared marketing materials and hired new employees. Simultaneously, Andrx officials began to discuss with their counterparts at HMRI the possibility of entering into an agreement under which Andrx would postpone the marketing of its generic equivalent to Cardizem CD.

51. On September 17, 1997, the FDA gave preliminary approval to Andrx's Amended ANDA for its generic version of Cardizem CD. Such approval meant that on July 8, 1998 (or sooner, if the patent case was resolved), Andrx would be free to enter the market. Upon information and belief, Andrx fully intended to market its product as soon as it was legally permitted to do so, unless it could secure an agreement with HMRI, by which HMRI would compensate it for refraining from selling its generic alternative to Cardizem CD. But for the agreement with HMRI, Andrx would have begun marketing its generic version of Cardizem CD on or shortly after July 8,1998.

D. HMRI and Andrx's Illegal Agreement

52. On September 24, 1997, one week after Andrx received preliminary FDA approval for its amended ANDA, HMRI and Andrx entered into the HMRI/Andrx Stipulation and Agreement (the "Agreement" or "the HMRI-Andrx Agreement").

53. The Agreement delayed the appearance of a generic competitor to Cardizem CD, guaranteed that HMRI would maintain its 100% share of the market for Cardizem CD and its AB-rated bioequivalents, and effectively insured HMRI's continued dominance over the once-a-day diltiazem prescription drug market. Under the Agreement, Andrx promised not to sell a generic version of Cardizem CD, regardless of whether its product infringed HMRI's patent, unless Andrx obtained a license from HMRI under terms specified in the Agreement, or HMRI provided Andrx with notice that it intended to license Cardizem CD to a third party. The Agreement was to last until the entry of a final judgment in the patent litigation.

54. In addition to withholding its product from the market, Andrx agreed to diligently prosecute its ANDA, so as to preserve its right to the Exclusivity Period, and not to relinquish any right to which it was entitled thereunder during the pendency of the Agreement, including selling or

transferring its right to the Exclusivity Period. Since the Exclusivity Period would not begin to run until Andrx actually entered the market or the patent lawsuit was resolved, the Agreement effectively blocked any other manufacturer from selling a generic version of Cardizem CD. Indeed, the sole benefit HMRI received from these contractual terms was to shield Cardizem CD from competition from other potential generic entrants. On information and belief, in or about July 1998, there was at least one generic manufacturer who was prepared to purchase Andrx's rights as first filer and enter the market with a generic version of Cardizem CD, and who made an offer to Andrx to that effect.

55. HMRI paid heavily to maintain its monopoly in this profitable market. Pursuant to the Agreement, HMRI was obligated to start making quarterly "interim payments" to Andrx of $10 million each as of July 9, 1998, the day after Andrx otherwise could have entered the market. The payments would not terminate until the patent case reached final resolution, including all appeals. If Andrx won the case, HMRI had to pay Andrx an additional $60 million per year from July 9, 1998 until the date that the final judgement became effective, bringing Andrx's total payments to $100 million per year of delayed entry. If Andrx lost the patent suit, the Agreement would still provide Andrx with a licensing option.

56. The Agreement specifically did not settle the patent litigation, and was not presented to the court handling that case. Indeed, the Agreement required the parties to keep its terms a secret, and stated explicitly that it was never to be filed in any court proceeding.

57. In September 1998, Andrx filed a supplement to its ANDA, specifying a 65% dissolution profile for its product. This amendment further undermined the already remote possibility that HMRI's infringement action against Andrx would be successful.

58. On June 9, 1999, following the commencement of private antitrust litigation based on the Agreement, HMRI and Andrx announced that they had agreed to settle their patent suit. They claimed that the settlement had been made possible by Andrx's ANDA amendments, and its concomitant reformulation of its generic version of Cardizem CD. At the time of settlement, HMRI paid Andrx an additional $50,700,000, bringing its total payments to Andrx to $89,830,000.

59. On June 23, 1999, Andrx began marketing Cartia XT, its generic alternative to Cardizem CD. Cartia XT sold for approximately 10% less than Cardizem CD. Within six months, HMRI's share of the market for Cardizem CD and its AB-rated bioequivalents dropped to approximately 50%.

60. Because of HMRI's Agreement with Andrx, and the resulting delay in Andrx's entry into the market, Andrx's Exclusivity Period did not finally expire until December, 1999.

61. In July 1999, generic drug manufacturer Purepac received final FDA approval for its generic version of Cardizem It settled its patent litigation with HMRI by entering into a licensing agreement, which permitted Purepac to sell its generic alternative. However, Purepac could not come to market until December 1999, when Andrx's Exclusivity Period expired.

62. In October, 1999, the FDA approved Biovail's ANDA for its generic version of Cardizem CD. Biovail also could not sell its product at that time, because of the bottleneck created by Andrx's exclusive right to market a generic version of Cardizem CD.

63. Once all three generic competitors to Cardizem CD reached the market, HMRI's market share plummeted to 30%. The prices of the generic drugs also fell, until they were available at 60% less than the brand-name price.

64. On June 6, 2000, Federal District Court Judge Nancy Edmunds issued a Memorandum Opinion and Order Granting Plaintiffs' Motion for Partial Summary Judgment, which ruled that Defendants' September 24, 1997 Agreement constituted a *per se* violation of Section One of the Sherman Act. *In Re: Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, (E.D. Mich. 2000).

V.
RELEVANT MARKET

65. A relevant product market for assessing Defendants' anticompetitive acts is the market for Cardizem CD and its FDA-approved, AB-rated, bioequivalents. Under FDA regulations, once a physician prescribes Cardizem CD, the patient may only purchase that drug or its AB-rated bioequivalent. Other once-a-day diltiazem medications cannot be substituted by the pharmacist or consumer without a new prescription. Thus, from the perspective of consumers, the prescribing practices of their physicians limit consumers' purchasing options to the prescribed brand-name drug, and its approved AB-rated generic alternatives, if any.

66. Until the entry of Cartia XT, HMRI had an absolute monopoly in this market.

67. Alternatively, a relevant product market for assessing Defendants' anticompetitive acts is the market for once-a-day extended release diltiazem prescription drugs. Neither other forms of diltiazem, nor other medications for treatment of hypertension and prevention of heart attacks, effectively compete with once-a-day diltiazem.

68. Until the entry of Cartia XT, HMRI had an effective monopoly in this market.

69. The relevant geographic market is the United States.

VI.
INTERSTATE COMMERCE

70. At all times relevant to this Complaint, HMRI and its successor Aventis have participated in the market for Cardizem CD and its FDA-approved, AB-rated, bioequivalents, or alternatively, the market for once-a-day diltiazem prescription drugs in the United States. At all times relevant to this Complaint, Defendant Andrx either prepared to, or did in fact, participate in this market.

71. The activities of the Defendants, including manufacturing, marketing, distributing and selling pharmaceutical products, were in the regular, continuous and substantial flow of interstate commerce and have had and continue to have a substantial effect on interstate commerce.

VII.
EFFECTS OF DEFENDANTS' ILLEGAL CONDUCT

72. The Defendants' acts and practices had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition within each State and throughout the United States, by:

(a) depriving direct and indirect purchasers of Cardizem CD of less expensive, comparable, generic alternatives;

(b) maintaining the monopoly price of Cardizem CD for pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, consumers, and others who purchased Cardizem CD, but who would otherwise have purchased a generic alternative, if one were available;

(c) delaying the establishment of MAC prices and restricting the negotiation of larger discounts or rebates for both Cardizem CD and its generic alternatives;

(d) depriving consumers of the benefits of competition among generic pharmaceutical manufacturers and delaying the entry of new competitors;

(e) depriving consumers of access to needed pharmaceuticals, and thereby injuring their health; and

(f) injuring the States' economies, by engaging in collusive behavior that distorted the process of free and open competition.

73. Many of the injured purchasers, including bureaus, agencies and departments of state governments, purchase generic drugs, when they are available, as a matter of policy or practice. Defendants' anticompetitive acts deprived these purchasers of the ability to implement such policies or practices, and to select a cheaper alternative to Cardizem CD or to obtain Cardizem CD less expensively.

74. The Defendants' acts and practices had the purpose or effect, or the tendency or capacity, and did unjustly enrich the Defendants.

VIII.
INJURY

75. As a direct and proximate result of the unlawful conduct alleged above, from July 1998 through June 1999, the States and consumers residing therein were not able to purchase a generic version of Cardizem CD, and they have consequently been injured in their business and property in that, *inter alia*, they have paid more for once-a-day diltiazem prescription drugs than they would have paid but for HMRI's and Andrx's anti-competitive practices, because they were unable to purchase generic alternatives to Cardizem CD that would have been available but for Defendants' acts.

76. As a direct and proximate result of the unlawful conduct alleged above, consumers in the Plaintiff States paid, and continue to pay, higher prices for Cardizem CD and/or the generic versions of Cardizem CD now available, because of the delay caused by HMRI's and Andrx's anti-competitive conduct, and its effect on generic price decreases, larger discounts and larger rebates that inevitably appear upon the entry of multiple generic competitors.

77. As a direct and proximate result of the unlawful conduct alleged above, the States have sustained injury, and are threatened with further injury unless the Defendants are enjoined from engaging in similar unlawful conduct in the future. The States do not have an adequate remedy at law for such conduct.

78. As a direct and proximate result of the unlawful conduct alleged above, HMRI has unjustly profited by maintaining a higher share of the market for once-a-day diltiazem than it would have enjoyed absent its anti-competitive acts, and by maintaining a 100% share of the market for Cardizem CD and its AB-rated bioequivalents. Andrx has unjustly profited by receiving payments pursuant to an illegal and unreasonable agreement in restraint of trade, and by delaying competition from other generic entrants.

IX.
FIRST CLAIM FOR RELIEF
VIOLATION OF SECTION 1
OF THE SHERMAN ACT

79. The States repeat and reallege paragraphs 1 through 78.

80. From September 1997 until June 1999, Defendants engaged in a continuing combination, conspiracy, and arrangement in unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

81. The combination, conspiracy, and arrangement consisted of an agreement between and among HMRI and Andrx to allocate to HMRI the market for Cardizem CD and its AB-rated bioequivalents, or alternatively, the market for once-a-day extended release diltiazem prescription drugs, by keeping Cardizem CD free from generic competition from July 1998 through June 1999, and further delaying the entry of other generic competitors thereafter. In return for postponing its own entry, and thereby delaying all generic entry into the market, Andrx received nearly $90 million from HMRI. This combination, conspiracy, arrangement and agreement was in violation of Section 1 of the Sherman Act.

82. By delaying entry of generic versions of Cardizem CD, HMRI denied consumers access to less expensive, medically equivalent alternatives to its product, thus causing consumers, government agencies and others who purchase or reimburse others for the purchase of Cardizem CD to pay more than they would have under natural conditions of competition in the absence of such illegal restraints of trade. The restraint also impeded the establishment of larger discounts, rebates or other price caps which would have resulted in lower prices for Cardizem CD and/or its generic alternatives.

X.
SECOND CLAIM FOR RELIEF
MONOPOLIZATION OF THE MARKET FOR CARDIZEM CD AND ITS BIOEQUIVALENTS, OR ALTERNATIVELY, THE MARKET FOR ONCE-A-DAY DILTIAZEM PRESCRIPTION DRUGS, IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT.

83. The States repeat and reallege paragraphs 1 through 78.

84. HMRI has engaged in exclusionary, anti-competitive conduct designed to prevent

competition on the merits between HMRI and its generic competitors, including but not limited to: a) the formation of an illegal agreement with Defendant Andrx; and b) engaging in various efforts intended to prevent or induce Biovail to refrain from marketing a generic alternative to Cardizem CD. These Acts were intended to and did allow HMRI to maintain its monopoly power in the market for Cardizem CD and its AB-rated bioequivalents, or alternatively, in the market for once-a-day diltiazem prescription drugs, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XI.

THIRD CLAIM FOR RELIEF
ATTEMPTED MONOPOLIZATION OF THE MARKET FOR CARDIZEM CD AND ITS BIOEQUIVALENTS, OR ALTERNATIVELY, THE MARKET FOR ONCE-A-DAY DILTIAZEM PRESCRIPTION DRUGS IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

85. The States repeat and reallege paragraphs 1 through 78.

86. HMRI engaged in a course of exclusionary conduct in order to obtain or maintain its monopoly over the markets for once-a-day diltiazem and for Cardizem CD and its AB-rated bioequivalents including: a) the formation of an illegal agreement with Defendant Andrx; and b) engaging in various efforts intended to prevent or induce Biovail to refrain from marketing a generic alternative to Cardizem CD.

87. At all relevant times, HMRI acted with a specific intent to monopolize, and to destroy competition in the market for Cardizem CD and its AB-rated bioequivalents, or alternatively in the market for once-a-day diltiazem prescription drugs, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

88. At the time HMRI engaged in these acts, it had a dangerous probability of succeeding

in obtaining or maintaining a monopoly on the sale of Cardizem CD and its AB-rated bioequivalents and alternatively on the sale of once-a-day diltiazem prescription drugs.

XII.

SUPPLEMENTAL STATE LAW CLAIMS

89. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 78.

90. Defendants' acts violate New York General Business Law §§ 340-347, and constitute fraudulent or illegal acts under New York Executive Law § 63(12) and deceptive acts under New York General Business Law § 349.

91. Plaintiff State of Michigan repeats and realleges each and every allegation contained in Paragraphs1 through 78.

92. Defendants' acts violate the Michigan Antitrust Reform Act MCL 445.771 *et seq.* Specifically, but without limitation, Michigan is entitled to redress pursuant to MCL 445.777 and MCL 445.778.

93. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 78.

94. Defendants' acts violate the Arizona Uniform State Antitrust Act, A.R.S. § 44-1401 *et seq.* Specifically, but without limitation, Defendants' practices are in violation of A.R.S. §§ 44-1402 and 44-1403.

95. Plaintiff State of California repeats and realleges each and every allegation contained in Paragraphs 1 through 78.

96. Defendants' acts violate California's Cartwright Act, Cal. Bus. & Prof. Code §§16720 *et seq.* and California's Unfair Competition Act, Cal. Bus. & Prof. Code §§17200 *et seq.*

97. Plaintiff District of Columbia repeats and realleges each and every allegation contained in Paragraphs 1 through 88.

98. Defendants' acts were in violation of the District of Columbia Antitrust Act, specifically D.C. Code §§ 28-4502 and 28-4503. The laws of the District of Columbia are included in the term "state law" as used in this complaint.

99. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 78 .

100. Defendants' acts violate the Idaho Competition Act, Idaho Code § 48-101 *et seq.* (2000 Supp.) Specifically, but without limitation, Defendants' acts violate Idaho Code §§ 48-104 and 48-105 (2000 Supp.).

101. Plaintiff State of Indiana repeats and realleges each and every allegation contained in paragraphs 1 through 78 .

102. Defendants' acts violate the Indiana Code §§ 24-1-1-1, 24-1-2-1, and 24-1-3-1.

103. Plaintiff State of Maine repeats and realleges each and every allegation contained in paragraphs 1 through 78.

104. Defendants' acts violate the Maine "mini-Sherman Act," 10 M.R.S.A. §1101 *et seq.*, and the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*

105. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 78.

106. Defendants' acts violate the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66.

107. Plaintiff State of New Mexico repeats and realleges each and every allegation contained in paragraphs 1 through 78.

108. Defendants' acts violate the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq.* NMSA (1978) and the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1 *et seq.* (1978).

109. Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 78.

110. Defendants' acts violate N.C. Gen. Stat. §§ 75-1 *et seq.*

111. Plaintiff State of Oklahoma repeats and realleges each and every allegation contained in paragraphs 1 through 78.

112. Defendants' acts violate the Oklahoma Antitrust Reform Act , 79 O.S. § 201 *et seq.* (1998) and the Oklahoma Consumer Protection Act ("OCPA"), 15 O.S. § 751 *et seq.*

113. Plaintiff State of Utah repeats and realleges each and every allegation contained in paragraphs 1 through 78.

114. Defendants' acts violate the Utah Antitrust Act, Utah Code Ann. §§ 76-10-911 through 76-10-926 (1999 Replacement, as amended) and the common law of Utah. Specifically, but without limitation, Defendants' acts violate Utah Code Annotated § 76-10-914(1) and § 76-10-914(2).

115. Plaintiff State of Vermont repeats and realleges each and every allegation contained in Paragraphs1 through 78.

116. Defendants' acts violate the Vermont Consumer Fraud Act, 9 Vermont Statutes Annotated Chapter 63, and the common law of Vermont. Specifically, but without limitation, the aforementioned practices violate 9 V.S.A. §2453.

117. Plaintiff State of Washington repeats and realleges each and every allegation contained in Paragraphs1 through 78.

118. Defendants' acts violate Wash. Rev.Code 19.86.010 *et seq.*

119. Plaintiff State of West Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 78.

120. Defendants' acts violate the West Virginia Antitrust Act, W.Va. Code § 47-18-1 *et seq.* and the West Virginia Consumer Credit and Protection Act, W.Va. Code § 46A-1-101 *et seq.*

XIII.
RELIEF REQUESTED

Accordingly, the Plaintiff States request judgment as follows:

121. Adjudge and decree that Defendants have engaged in conduct in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

122. Adjudge and decree that Defendants have engaged in conduct in violation of the state statutes enumerated in Paragraphs 89 to 120;

123. Enjoin and restrain, pursuant to federal and state law, the Defendants, their affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and

employees, and all other persons acting or claiming to act on their behalf or in concert with them, from engaging in any conduct, contract, combination or conspiracy, and from adopting or following any practice, plan, program or device having a similar purpose or effect to the anti-competitive actions set forth above;

124. Enter judgment for the Plaintiff States and award all other available equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds necessary to redress Defendants' violations of state and federal law and/or the unjust enrichment of the Defendants;

125. Enter judgment for the Plaintiff States for three (3) times the amount of damages sustained by the States as purchasers or assignees of purchasers of Cardizem CD, as allowed by federal law;

126. Enter judgment for the Plaintiff States of California, Maine, Minnesota, New Mexico, New York, North Carolina, Vermont, and West Virginia against Defendants, jointly and severally, for three (3) times the amount of damages sustained by the Plaintiff States and their agencies (including medical reimbursement programs) as purchasers or assignees of purchasers of Cardizem CD, as allowed by state law;

127. Enter judgment for the Plaintiff States of Arizona, Michigan, Oklahoma, Utah, and Washington, and for the District of Columbia, against Defendants, jointly and severally, for the amount of damages sustained by the States and their agencies (including medical reimbursement programs) as purchasers or assignees of purchasers of Cardizem CD, as allowed by state law;

128. Enter judgment for the Plaintiff States of Arizona, California, Maine, Michigan, Minnesota, New Mexico, New York, North Carolina, Vermont, and Washington, and for the District of Columbia, against Defendants, jointly and severally, and award damages sustained by the States,

their agencies, and the entities and persons they represent or on whose behalf this suit is brought, for indirect purchases of Cardizem CD, to the full extent permitted by state law;

129. Enter judgment for the States of Arizona, California, Idaho, Maine, Michigan, Minnesota, New Mexico, New York, North Carolina, Utah, Vermont, Washington, and West Virginia against Defendants for the maximum civil penalties permitted by state law;

130. Award each State the costs of this action, including reasonable attorneys' fees, and, where applicable, expert fees; and

131. Grant such other and further relief as may be just and proper.

XIV.
JURY TRIAL DEMAND

Plaintiffs demand trial by jury pursuant to Rule 38(b) of the Federal Rules of Civil Procedure on all issues triable of right by a jury.

Respectfully Submitted,

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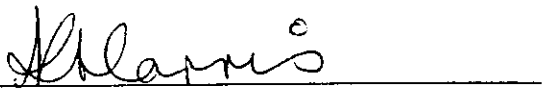

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